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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/601,314 | 06/20/2003 | Jian Zhao | NASH-001/03US | 6959 |
| 23419 | 7590 | 11/16/2004 | EXAMINER | |
| COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306 | | | DENTZ, BERNARD I | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,314

Applicant(s)

ZHAO ET AL.

Examiner

Bernard Dentz

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17-27, 30-33, 36, 37, 39-57 and 60-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 28, 29, 34, 35, 38, 58 and 59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/10/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Applicants have elected Gp.III without traverse. Claims 17, 61 and 62 should be in Gp. II. Thus claims 15,16, 28, 29, 34, 35, 38, 58 and 59 are under examination. Non-elected claims 1-14, 17-27, 30-33, 36, 37, 39-57 and 60-74 are withdrawn from consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15,16,28,29,34,35,38,58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Vitasyn, DE 19627344 A1 cited by applicants. An English translation will be used in the explanation. The reference discloses the benefits of the polyphenol constituents of both green tea and of its fermented form, which is black tea, in the treatment of hyperlip[idemia. The polyphenol constituents of black tea are called theaflavins. See p. 2 of the English translation. See claim 1 for the claiming of the pharmaceutical composition containing theaflavins and claim 14 for its use in treating hypercholesteremia. See claims 18 which uses the composition of claim 1 to treat disturbances in lipid metabolism.

Note that although use of the constituents of green tea is stressed the above constituents of black tea are also included. In this vein see p. 9, line 10 starting with “Black tea is prepared by subjecting it” (refers to green tea of the previous sentence) “to a fermentation process, which is characterized primarily by the oxidation and

polymerization of the polyphenols. The fermentation produces significant changes in the polyphenol functions." This is obviously describing the change of the catechins of the green tea to the theaflavins characteristic of black tea.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15,16, 28,29,34, 35, 38, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitasyn, supra. The anticipation rejection is strong but in case it is overcome this obviousness rejection is made. The reference teaches the beneficial anti-oxidant effect of the instant theaflavin ingredients and their use in the treatment of liver diseases, reduction of blood sugar level, the prophylaxis and therapy of hypercholestermia, in reducing elevated serum triglycerides, in improving the atherogenic index in persons with cardiovascular risk factors, in the prophylaxis and therapy of arteriosclerosis, etc. at p. 11-13 of the translation. Therefore any slight difference in the wording of a treatment of a disease state between the instant claims and the reference would have been obvious to one of ordinary skill in the art due to its recognition and description of the great health benefits accorded by consumption of the instant ingredients.

Claims 15, 16, 28, 29, 34, 35, 38, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Abe et al, Japanese Journal of Food Chemistry. It discloses that the theaflavins in black tea are excellent inhibitors of squalene epoxidase, the rate-

limiting enzyme of cholesterol biosynthesis. See p. 47, col. 2, first sentence of first complete paragraph. Thus basically the method of treating or preventing hyperlipidemia by administering to a patient in need thereof ^{with} a theaflavin mixture e.g. black tea is anticipated.

Claims 15, 16, 28, 29, 34, 35, 38, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al. Thus because of the above and because of "therefore, like green tea, black tea would be expected to be an excellent beverage for lowering cholesterol well as cancer prevention" appearing at p. 49, col. 1 the instant use of theaflavins would have been obvious to the ordinarily skilled in the art

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571 273-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz
11/8/2004

B. Dentz

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